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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,840	03/15/2004	Gordon J. Dow	2102.010US2	1530
21186	7590	11/01/2006	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER

1617

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,840

Applicant(s)

DOW ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 45-64 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/15/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This is a continuation application of US Serial 09/830,037, which is a national stage entry of PCT/GB99/03472, filed 10/20/1999.

Claims 45-64 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill (WO 92/14472) and Gordon (Clinical therapeutics, 1998; 20(1): 26-39) in view of Richards (US Patent 4,985,418), and Budavari (Merck Index 11th ed. 1989, monograph 6021 and 7879) references of record in the parent application.

Hill teaches a topical composition employing 0.05% of the corticosteroid, fluticasone propionate, 10.00% of cetostearyl alcohol, 10% of White Soft Paraffin, 2.50% of Polysorbate 60, 10.00% of propylene glycol, and purified water (see particularly Example 1). Hill also teaches that the topical composition is useful in treating skin conditions including inflammation (See particularly page 1, 6th paragraph).

Gordon teaches a corticosteroid (clobetasol) containing composition, free of mineral oil and white soft paraffin, employing Cetostearyl alcohol, cetomacrogol 1000, Isopropyl myristate, propylene glycol, Dimethicone 360, citric acid, sodium citrate, imidurea, and water (see page 28, table 1). Gordon also teaches the function for

adding occlusive agents in emollient cream will help moistening the skin (See page 32, col. 2). Gordon also teaches the absorption of the steroids is greater when more occlusive agents are present in the formulation (See page 32, col. 2).

The references do not expressly teach the composition with the specific amount of white paraffin. The references do not expressly teach the employment of methyl paraben and propyl paraben in the lotion. The references do not expressly teach the weight percentage of surfactant to be about 0.5 to 2.0%.

Richards teaches that methyl paraben and propyl paraben are excipients known to be useful in a fluticasone topical composition (See particular col. 5, lines 20-30). Richards also teaches the preparation of the fluticasone composition involving the process of mixing the ingredients at 70 degree Celsius and then heating the mixture to 70 degree (See particular col. 6, line 10-17).

Budavari teaches both methyl parabena nd propyl paraben are useful as preservatives and pharmaceutic aids (See the Use section of the monographs).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to formulate a topical fluticasone composition as free of mineral oil and white soft paraffin with the ingredients herein in the amount herein. It would have also been obvious for one of ordinary skill in the art at the time the invention was made to prepare a topical fluticasone composition that has the herein claimed amount of surfactant.

One of ordinary skill in the art would have been motivated to formulate a topical fluticasone composition, as free of mineral oil and white soft paraffin, with the excipient

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ingredients in the amount herein. Possessing the teachings of the cited prior art, one of ordinary skill in the art would be reasonably expected to successfully substitute clobetasol with fluticasone to formulate an emollient cream as up to 5% of mineral oil and white soft paraffin. Furthermore, the excipients herein are known to be useful in formulating topical corticosteroid compositions. Therefore, incorporating all the excipients herein with any known active corticosteroid compounds including fluticasone would have been reasonably expected to be useful in preparing the topical fluticasone composition herein. Furthermore, the optimization of desired effect parameters (amount of excipients) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



San-ming Hui
Primary Examiner
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